Facsimile Cover Sheet

MEDLEN & CARROLL LLP

TO: Director John Doll (fax - 703-305-7230)

and

Examiner Tekchand Saidha (fax - 703-305-3014)

FROM: David A. Casimir, J.D., PhD.

Date: August 13, 2004 Time: 5:00 p.m.

Pages (including cover): 24 **Group No: 1652**

Dear Director Doll and Examiner Saidha,

Please find attached to this cover sheet a Reissue Application Protest under 37 C.F.R. 1.291 to Address New Issues, submitted in opposition to **reissue application 09/586,744**. Complete copies of this Reissue Application Protest are being mailed today to the Patent Office and to the attorney of record for Applicants by Express Mail.

Sincerely,

David A. Casimir
Reg. No. 42,395
608-218-6900

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Harrington *et al.*
Serial No.: 09/586,744
Filed: 06/02/00
Entitled: **Mammalian Flap-Specific Endonuclease**

Group No.: 1652
Examiner: T. Saidha

PROTEST TRANSMITTAL LETTER

Assistant Commissioner for Patents
ATTN: Technology Center 1600 - Director Doll
P.O. Box 1450
Alexandria, VA 22313-1450

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.10

I hereby certify that this correspondence (along with any referred to as being attached or enclosed) are being deposited with the U.S. Postal Service on **August 13, 2004** in an envelope as "EXPRESS MAIL POST OFFICE TO ADDRESSEE" service under 37 C.F.R. § 1.10, Express Mail Label Number **EV 473 000 170 US** addressed to: Commissioner for Patents, ATTN: Technology Center 1600 - Director Doll, P.O. Box 1450, Alexandria, VA 22313-1450

By: Susan M. McClintock
Susan M. McClintock

REMARKS

This is a Protest Under 37 C.F.R. 1.291 to Address New Issues for application no. Re. 09/586,744, filed 06/02/00. Third Party Protestors believe no fee is required but if the Commissioner deems otherwise he is authorized to charge Deposit Accout No. 08-1290.

A copy of this Protest is also being forwarded on this day to counsel of record: Dorsey & Whitney LLP, ATTN: Birgit Millauer, Four Embarcadero Center, Suite 3400, San Francisco, CA 94111-4187 in an envelope as "Express Mail Post Office to Addressee" service under 37 C.F.R. 1.10, Express Mail Label No. EL 658 779 263 US.

DATE: August 13, 2004

By: _____
David A. Casimir
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Harrington *et al.*		
Serial No.:	Re. 09/586,744	Group No.:	1652
Filed:	06/02/00	Examiner:	T. Saidha
Entitled:	**MAMMALIAN FLAP-SPECIFIC ENDONUCLEASE**		

REISSUE APPLICATION PROTEST UNDER 37 C.F.R. 1.291 TO ADDRESS NEW ISSUES

Assistant Commissioner for Patents
ATTN: Technology Center 1600 - Director Doll
P.O. Box 1450
Alexandria, VA 22313-1450

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Dated: August 13, 2004

By: Susan M. McClintock
Susan M. McClintock

Sir:

The following communication is presented to protest reissue application 09/586,744. Specifically, this communication is directed toward new issues that could not have been addressed in the previously filed Protests (mailed January 3, 2001 and January 9, 2002).

REMARKS

In the first filed Protest, four issues were addressed that are distinct from the new issues discussed in this communication. For the Examiner's convenience, the four issues are summarized below such that it is clear that the new issues presented herein are new issues that could not have been presented in the first filed Protest. Copies of the previous Protests are also attached for the Examiner's convenience.

1. In the first Protest, it was pointed out that no proper "error" was identified or alleged, as required for a reissue application. Instead, Applicants seek to claim non-

elected subject matter that was given up without traverse in the face of a restriction requirement. Applicants did not pursue the non-elected claims or any other inventions in either a divisional or continuation application, and thus gave up the rights to such claims. Under controlling case law, this was a *choice*, not an error warranting reissue. Therefore, as a matter of law, the reissue cannot proceed.

2. In the first Protest, it was pointed out that the new claims are directed to separate and distinct subject matter that is not the "same invention," as required for a proper reissue application, and therefore, as a matter of law, the reissue cannot proceed. For example, the first Protest highlighted the fact that the inventors themselves admit in sworn declarations that at the time the original application was filed, they had not conceived of the alleged invention that is now claimed in the sixty-seven (67) new claims.

3. In the first Protest, it was pointed out that all of the claims sought to be added were drafted more broadly than the original six claims, which were limited to genes for enzymes from particular organisms. The new patent owner is attempting to improperly recapture what was surrendered during the prosecution of the application, and therefore, as a matter of law, the reissue cannot proceed. Having surrendered the broader claims, as highlighted in the first Protest, Applicants cannot then use the reissue process to resurrect this subject matter.

4. In the first Protest, it was pointed out that all sixty-seven added claims were unsupported by the original specification. To cover this deficiency, the Applicants are improperly attempting to bodily incorporate the contents of a non-patent document to provide support that is essential for the new claims. Therefore, as a matter of law, the reissue, cannot proceed. The first Protest also highlighted the fact that, even with such an improper amendment of the specification, all of the claims are still unsupported.

In the second filed Protest, two issues were addressed that are distinct from the new issues discussed in this communication.

1. In response to the Examiner's New Matter rejection, Applicants alleged that they

have made a *specific* incorporation of double-flap structures. However, the case law cited by Applicants failed to support Applicants' position. In addition, Applicants failed to disclose that the '283 specification *specifically contradicts* incorporation of double-flap structures.

2. In response to the Examiner's Written Description rejection, Applicants attempted to re-define double-flap structures in a manner *inconsistent* with the '283 specification's clear definition of 3' flap structures. This attempt to re-define double flap structures as outside the definition of 3' flap structures is important since the '283 specification specifically recites that 3' flap structures are not cleaved by FEN-1.

The present communication addresses five new issues based on Applicants' arguments to the patent office in their August 13, 2003 Amendment ("2003 Amendment") and their May 18, 2004 Amendment ("2004 Amendment").

1. In the 2003 and 2004 Amendments, Applicants have mischaracterized their disclosure of FEN-1 endonucleases to overcome written description rejections.
2. In the 2003 Amendment, Applicants admitted that the claimed invention is a different invention than that claimed in the original application. This admission mandates that the claims be rejected for failure to address an error that is correctable under reissue, because the statute forbids pursuing a different invention in a broadening reissue proceeding.
3. In the 2003 Amendment, Applicants misstated the law to the Examiner in an attempt to incorporate the "double flap" concept into the application.
4. In the 2003 Amendment, Applicants mischaracterized the specification of the present application in an attempt to incorporate the "double flap" concept into the application.
5. In the 2004 Amendment, Applicants amended and added *dependent* claims in an attempt to overcome the Examiner's probe length written description rejection. Despite assertions by the Applicants, this "amendment" is insufficient to overcome the Examiner's rejection, as the *independent* claims remain unamended and therefore lack proper written description support.

Protestors note that these arguments by Applicants represent new issues that differ from the previously addressed six issues. Because these issues were created by Applicants' latest Amendments and arguments, they could not have been presented in the previous Protests. As such, this protest is proper under 37 CFR 1.291, and should be thoroughly considered by the Examiner and made part of the public record of this reissue application.

These new arguments add additional bases for rejecting the pending reissue claims and provide support to bolster the Examiner's current rejections. A number of these new arguments relate to Applicants' incorrect and/or misleading statements or arguments. Applicants have failed to overcome the Examiner's rejections in the numerous previous responses and appear to be resorting to gamesmanship in an attempt to leverage allowance of claims that are improper for numerous reasons. It appears that Applicants are hoping to wear down the Examiner with continuous filings, interviews, and increasingly inaccurate advocacy. In particular, Protestors note that Applicants failed to file an Appeal in response to the Final Office Action mailed July 11, 2002. Instead, Applicants waited the full 13 months of extension to proceed with a Request for Continuing Examination. The delay and redirection avoided having the patent struck down by an Appeal Board that would uphold the Examiner's rejections and likely add additional bases of rejection (e.g., based on issues raised in this and prior Protests, which the Examiner has not pursued or has withdrawn, but which, under the law mandate rejection of the claims).

The Assignee of this application is trying to change the law. This Assignee, a large corporation, is attempting to secure a patent monopoly in a technology area in which it currently has no rights. In particular, the Assignee is seeking control over all methods using the cleavage of double-flap structures by the use of FEN-1 endonuclease enzymes. At present, the only patents covering such methods are owned by the Assignee's business competitors.

The Assignee purchased the present patent from a University researcher. The original patent relates only to nucleic acid molecules encoding a very specific and limited set of FEN-1 endonucleases. The patent makes no mention of double-flap structures, nor does it teach or claim the use of them in any methods. Nonetheless, the Assignee, now in control of this patent, is taking an unprecedented course of action: it has put the case into a broadening reissue process in an attempt to claim an invention not described in the original application and not contemplated by the original inventors. The Assignee is attempting an illegal incorporation-by-reference to add language in an attempt to provide support for an invention that is a pure hindsight construction.

If the Assignee wants to own rights to the invention now claimed, it is free to make a new application, subject to the rights that the public and other inventors have acquired in advance of the Assignees proper filing date. It is an egregious abuse of the system for this Assignee to attempt to purchase an earlier filing date by purchasing the patent of another, then refashioning that patent in a broadening reissue proceeding to claim inventions not conceived of by the original inventors.

The Patent Office has the duty and ability to shut down this abuse of the patent system. By checking this abuse at this administrative level, the Patent Office can avoid burdening the public with the enormous expense of reversing this improper hindsight-based re-invention in court.

The Examiner should encourage Applicants to take up their cause with the Appeal Board and the Federal Circuit (who will uphold the Examiner's rejections) or with Congress if they would like to try to change or re-interpret the law.

I. APPLICANTS HAVE MISCHARACTERIZED THE SPECIFICATION IN REPONSE TO THE EXAMINER'S WRITTEN DESCRIPTION REJECTIONS

The Examiner has properly rejected the claims for failing to provide a proper written description for the claimed "FEN-1 endonucleases".[1] In response to this rejection, the Applicants have argued that the specification provides "eight exemplary species" as being representative of the FEN-1 polypeptide genus. This statement is deceptive and improper. In particular, Applicants point to a few FEN-1 endonucleases that are described in the specification and four that are briefly mentioned in the specification without any characterization (*i.e.*, no sequence, no purification or isolation procedure, and uncharacterized even to the point of failing to show that the "FEN-1" activity seen in the four extracts was, in fact, from a FEN-1 endonuclease, as opposed to some other source). The claims recite methods and kits relating to double-flap cleavage. The specification provides zero examples of FEN-1 endonuclease that function in such methods and kits. Even if allowed to improperly incorporate the Harrington paper by reference into the specification, the Applicants have provided one species—not eight. Either way, there is no discussion in the specification of the use of any double-flap structure in methods or kits as

[1] (See, April 1, 2003 Advisory Action, pgs 5-6 and November 18, 2003 Office Action, pgs 7-8).

claimed.

In making their argument, Applicants state that all "eight" so-called FEN-1 endonucleases described in the specification provide support for the claimed subject matter. However, the claims (now 21-76) describe "double flap" structures. The "double flap" concept is derived solely from the Harrington & Lieber paper that has been improperly bodily incorporated into the application. This paper demonstrates a single FEN-1 endonuclease capable of resolving the "double flap" structure—not eight, not four, not two—only one. The specification provides zero examples. There is no evidence in the original specification or in the Harrington & Lieber paper that any other FEN-1 endonuclease is capable of resolving these "double flap" structures. Thus, Applicants are not entitled to the specific four FEN-1 endonucleases described by SEQ ID NO in the specification or the additional four so-called FEN-1 endonucleases allegedly described in the specification, let alone the genus "FEN-1 endonuclease".

In the 2004 Amendment, Applicants appear to believe that they have overcome the Examiner's rejection as the result of an Interview with the Examiner. In particular, Applicants state:

> "[a]s agreed during the Interview, applying the legal standard, and in particular in light of the recent *Rochester*[2] decision, a description of *eight* species in the context of claims reciting a method, a hybridization complex, and a kit for performing the method, constitutes adequate written description support for the recitation of a genus." (2004 Amendment, page 18).

Protestors remind the Examiner that the Specification does NOT teach that any of the recited enzymes can resolve a double-flap structure. Instead, only by resort to the H & L paper are Applicants able to point to a single FEN-1 polypeptide capable of resolving the double flap structure. It appears that Applicants are attempting to use the Interview process to avoid, or re-frame, the issues.

In regard to the *Rochester* case discussed during the Interview, it appears that this case has been mischaracterized by the Applicants as this case does not help Applicants' attempt to overcome the lack of written description for FEN-1 polypeptides capable or resolving double-flap structures. Contrary to Applicants' description in the 2004 Amendment, the *Rochester* case does not discuss that eight or some other number are enough to establish a genus. The court never discussed what number of species is enough to constitute a genus because the patentee did

not provide a single species. The claims in *Rochester* were found to lack proper written description because the specification failed to provide any compounds useful in the claimed method, with the court stating:

> "the '850 patent does not provide any guidance that would steer the skilled practitioner toward compounds that can be used to carry out the claimed methods -- an essential element of every claim of the patent -- and has not provided evidence that any such compounds were otherwise within the knowledge of a person of ordinary skill in the art. . . " (358 F.3d at 929).

In light of the court's holding in *Rochester*, and the fact that this case does not comment on the number of species needed to support a genus, the *Rochester* case is of no help to the Applicants.

The *Rochester case*, however, DOES support the Examiner's rejection. In the present case, Applicants have, at best, only provided one FEN-1 polypeptide related to the claims. They have not cited any evidence that one of skill in the art at the time of filing would know of other FEN-1 polypeptides capable of resolving double-flap structures. As such, under *Rochester*, the Applicants have failed to provide written description to the broad genus of FEN polypeptides capable of resolving double flap structures. Likewise, the Applicants have not provided support for the wide variety of FEN polypeptides from the diverse range of lower organisms. Thus, even if given credit for eight examples, eight is not enough to support the claimed genus. For example, Applicants provide no examples of thermostable FEN polypeptides derived from, for example, extreme thermophile bacteria and no suggestion of the nature of cleavage structures that are recognized and cleaved by such FEN polypeptides (*e.g.*, at higher temperatures where the hybridization behavior of nucleic acid will differ from its behavior in the low temperature conditions used for the single non-thermostable FEN polypeptide described in the Harrington paper).

In light of the above, Protestors submit that the Examiner should maintain this rejection. Protestors also suggest that the Examiner, in order to protect the public, make audio recordings of any future Interviews and make the transcript of the Interview part of the Official record. In this regard, any mischaracterizations of case law or patent specification by the Applicants, or other mischaracterizations, can be reviewed and commented on by the public.

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[2] *University of Rochester v. G.D. Searle & Co.*, 358 F.3d 916 (Fed. Cir. 2004).

II. APPLICANTS' ADMISSIONS ABOUT THE NATURE OF THE CLAIMED INVENTION IRREVOCABLY CONCEDE THAT THE REISSUE IS IMPROPER

A. The Claim Must Be Rejected As Failing To Claim The Same Invention

Applicants unequivocally admit on page 20 of the 2003 Amendment that the claims of the present reissue application are directed to a different invention than claimed in the original application. Specifically, Applicants state:

> . . . given the fact that the rejected claims are directed to methods of use and kits, and not to the FEN-1 polypeptide molecules *per se*. (emphasis added)

The reissue law forbids use of the reissue process to seek claims to a different invention than pursued in the original application. The purpose of reissue is to correct an error made in the original patent—*i.e.*, to correct an error made in claiming the invention of the original patent. Reissue cannot be used to claim a different invention.

The original patent application, as filed, claimed only FEN-1 nucleic acid and polypeptide **compositions** from particular organisms. The polypeptide claims were surrendered during a restriction requirement and nucleic acid composition claims directed to these specific organisms eventually issued. Now, the Applicants are attempting to claim methods and kits. Applicants *readily admit* that these claims are not the subject matter of the polypeptide claims of the original patent. Likewise, these new claims are not the subject matter of the issued claims to the nucleic acid compositions encoding the polypeptides. **This ends the reissue**. There is no flexibility on this issue. The Examiner must reject the claims as being to a separate invention in view of Applicants admission. (MPEP 1412.01, *citing In re Amos*, 953 F.2d 613, 618 (Fed. Cir., 1991).

Importantly, Applicants' attempt to claim a different invention is further exaggerated by directing the claims to **methods** and **kits** involving a "**double flap**" structure, subject matter that was not disclosed in the original application in a manner that would have allowed the inventors to claim this subject matter during the prosecution of the original application (see Section III, below for a description of the impropriety of now attempting to incorporate the double flap subject matter through incorporation by reference). The inventors could not have appreciated an invention to methods and kits involving the cleavage of double-flap structures when no such description was in the original application. This disclosure is not in the application even if the

Harrington reference in improperly incorporated—as the Harrington reference does not teach or suggest methods of kits involving double-flap structure since the double-flap structure simply appears in a control experiment with no comment on relevance or application.

The MPEP requires that the reissue claims must be for the *same* invention. MPEP 1412.01. The Federal Circuit has indicated that the proper test to determine whether the reissue claims are for the same invention is to ascertain whether "one skilled in the art, reading the specification, would identify the subject matter of the new claims as invented and disclosed by the patentees" (MPEP 1412.01, *citing In re Amos*, 953 F.2d 613, 618 (Fed. Cir., 1991). Applicants' original claims were not directed to the invention now being claimed and there is no basis within the original specification by which one skilled in the art would know or appreciate Applicants have allegedly invented and disclosed the subject matter of the new claims.

All three inventors state in their reissue declarations that "[a]t the time the original patent issued, Applicants failed to recognize that the application as filed disclosed patentable inventions beyond those originally and ultimately claimed" (*emphasis added*). This is fatal to Applicants' request for reissue. Applicants are skilled in the art. If they failed to recognize the subject matter later claimed, certainly others skilled in the art, who are not as close to the particular subject matter, would not recognize the subject matter later claimed. As such, Applicants have admitted that they fail the 'same invention' test as articulated in *In re Amos*. Applicants have admitted that they were not in possession of the alleged invention at the time the original application issued, and now admit that claims 21-76 are not the same invention as originally claimed.

Applicants have asserted that they have provided § 112 support for the newly added claims. However, the "original patent" requirement in MPEP 1412.01 is for the purposes of determining if the same invention requirement has been met, not whether the Applicants have met the section 112 requirements in the disclosure. The Federal Circuit has recognized that simply meeting 112 requirements in reissue claims does not alone establish intent to claim (*See, In re Weiler*, 790 F.2d 1576, 1581-82, Fed. Cir., 1986, stating:

> "It is true that absence of compliance with § 112 will foreclose a finding of "intent" and preclude grant of the reissue, but, as indicated above, the absence dooms the application in any event. The converse is not true. Compliance with § 112 does not alone establish "intent to claim" and does not alone establish error in a failure to claim".

Thus, even if the Applicants show proper 112 support for the new claims (which they cannot), the reissue is improper for attempting to claim a different invention. All of Applicants' arguments about satisfying Section 112 are not only erroneous, they are irrelevant to the "same invention" requirement.

The U.S. Supreme Court has squarely addressed this situation where an Applicant is attempting to claim a different invention by amendment of the specification during reissue with material that was ancillary to the original specification. In particular, in *Parker & Whipple Co. v. Yale Clock Co.*, 123 U.S. 87, 8 S.Ct. 38, (1887), the Supreme Court indicated that the invention of a reissue patent must be the invention described in the specification of the original patent, and a reissue attempting to claim (as part of the invention) embodiments shown in a model accompanying the original application (that were not claimed in the original application as forming part of the original invention) is void. Likewise, in the present application, the incorporated by reference of "double flap" subject matter and method and kits claims directed to this subject matter cannot now (in reissue) be added to the specification to support the pursuit of newly added claims that were unsupported and unclaimed by the original specification.

The Supreme Court in *Parker & Whipple Co.* recites the dangers in allowing an applicant to add additional material regarding a separate invention to a reissue application and then pursue claims based on this material:

> "The danger to be provided against was the temptation to amend a patent so as to cover improvements which might have come into use, or might have been invented by others, **after its issue**. The legislature was willing to concede to the patentee the right to amend his specification so as fully to describe and claim the very invention attempted to be secured by the original patent, and which was not fully secured thereby, in consequence of inadvertence, accident, or mistake; but was not willing to give him the right to **patch up his patent** by the addition of other inventions, which, though they might be his, had not been applied for by him, or, if applied for, had been abandoned or waived. For such inventions he is required to make a new application, subject to such rights as the public and other inventors may have acquired in the mean time." *(emphasis added, Parker & Whipple*, 123 U.S. 45-46).

As pointed out above, the new claims being pursued in this reissue application diverge dramatically from the claims originally patented and presented by the inventors as their original invention (*i.e.* the original claims are for polynucleotides encoding specific polypeptides, and the newly added reissue claims are for methods and kits). Over the past 125 years, courts have

struggled with the issue of whether it is permissible to present claims in a reissue application that, even though possibly related to the originally patented claims, are in a different statutory category (*e.g.* presenting method claims in a reissue application that directly correspond to the composition claims already patented). The courts have struggled with whether or not the newly added reissue claims are for the same invention as the originally patented claims, and/or whether failure to present these claims in the original application provided an acceptable basis of an alleged "error".

However, in the present case, Applicants have **gone far beyond** attempting to present claims in a different statutory category than the polynucleotide sequences originally patented. They are instead attempting to present a wholly separate invention that is unrelated to the polynucleotide sequences patented in the original patent. In other words, Applicants are not merely attempting to pursue methods of making the previously patented polynucleotide sequences, which would be questionable under current case law, but instead are attempting to pursue entirely different inventions (*e.g.* methods and kits containing a "double flap" structure). This is not proper and the law has no uncertainty in such cases -- such claims are forbidden according to controlling Supreme Court precedent.

In *Powder Co. v. Powder* Co., 98 U.S. 126, 25 L.Ed. 77, (1878), the Supreme Court firmly rejected an attempt by an Applicant to pursue such distinct inventions in a reissue application and explained that the reissue claims must be directly related to the original claims. The originally patented claims in the *Powder Co.* case were for a process for exploding nitroglycerine, whereas the reissue claims were for mixtures of nitroglycerine with gunpowder, guncotton, and rocket powder. The court concluded that "[i]nasmuch as the reissued patents in question ... are for compounds of nitroglycerine with various other substances, it is impossible not to say that they are for an entirely different invention from that secured, or attempted to be secured, by the original patent." *Id.* at 136. The following statement from *Powder Co.* is instructive:

> "The processes which the patentee described as his invention in the original patent, No. 50,617, had no connection with the compounds or mixtures which are patented in the reissued patents. They were not processes for making those compounds, and in describing them the compounds were not mentioned. The invention of the one did not involve the invention of the other. The two inventions might have been made by different persons, and at different times. We think, therefore, that the conclusion is irresistible, that the two reissued patents ... are for a different invention from that described or suggested

in the original patent." *(emphasis added, Id.* at 137).

Based on this reasoning, the Court in *Powder Co.*, held "[s]ince, therefore, the reissues in question are not for the same invention for which the original patent was granted, it follows that they are void ...". *Id.* at 139.

The *Powder* case provides bright line rules for determining whether other claim types may be added in reissue. The *Powder* case permits adding claims that are very closely inter-related, such as the addition of method claims involving *the production* of the originally claimed compositions. However, the addition of method claims that teach the diverse *uses* of the claimed compositions are NOT permitted.

Thus, in the present application, the newly presented reissue claims are clearly not for the same invention for which the original patent was granted. The Applicants admit this. Thus, there is nothing to debate. In particular, the original claims are to particular polynucleotide sequences encoding FEN-1 polypeptides, and host cells, while the newly added claims are directed to diagnostic methods and unrelated kits involving a "double flap" nucleic acid structure. Therefore, these reissue claims are void.

As such, based on Supreme Court precedent and Applicants' admissions, among other grounds, the Examiner must require Applicants to cancel newly presented reissue claims (i.e. claims 21-76) from this reissue application as violating 35 U.S.C. 251.

B. To The Extent The Claims Are Not Rejected As Failing To Claim The Same Invention, They Cannot Be Pursued Because They Are Directed To Surrendered Subject Matter

Should the Examiner not reject the claims for failure to claim the same invention as explained above, then claims 21-76 must be rejected as improperly trying to resurrect claims that were surrendered during prosecution—which does not qualify as "error" under the reissue laws.

If the current claims 21-76 are treated as being part of the same invention claimed in the original application, then they must be treated as being the same as one of the two inventions called out by the Examiner in the original restriction requirement. These new claims *must* be treated as being the same as the original "polypeptide" claims and not as the original "nucleic acid" claims. The present claims relate to kits and methods that contain or utilize a FEN-1

polypeptide—not claims that contain or use a nucleic acid encoding a FEN-1 polypeptide (*i.e.*, the kits are not kits containing FEN-1 nucleic acid for expressing FEN-1 polypeptides and the methods are not methods of expressing a FEN-1 polypeptide from FEN-1 nucleic acid). Thus, if the claims are part of the "same" invention, they are part of the "polypeptide" invention, not the "nucleic acid" invention.

In the original prosecution, Applicants acquiesced to the Patent Office position that the polypeptides are different inventions than the nucleic acids, and they surrendered the polypeptide invention in response to a restriction requirement. It is now impermissible to claim any subject matter corresponding to polypeptides. Thus, to the extent the Examiner does not reject the claims as failing to be the same invention, there is no choice but to reject the claims as improperly encompassing surrendered subject matter.

Having surrendered the polypeptide claims during the original prosecution, Applicants cannot now resurrect claims related to polypeptides in this reissue case. The law is unequivocal about this matter. MPEP 1402 states:

> A reissue applicant's failure to timely fail a divisional application is not considered to be error causing a patent granted on elected claims to be partially inoperative by reason of claiming less than the applicant had a right to claim. Thus, such applicant's error is not correctable by reissue of the original patent under 35 U.S.C. 251. (citing *In re Orita*, *In re Watkinson*, and *In re Mead*).

Thus, MPEP 1402 not only provides direction as to acceptable error, but specifically indicates that an applicant's failure to file a divisional application is not considered to be an acceptable error forming grounds for filing a reissue application. The Federal Circuit has explained that this 'lack of error' also applies to claim sets not originally presented in cases where a restriction requirement was made during original prosecution (*In re Weiler*, 790 F.2d1576, Fed. Cir. 1986).

During the prosecution of the original patent in this case, the Examiner restricted the claims into two groups. The Claims in Group I (Claims 1-5) were drawn to FEN-1 polypeptides and the Claims in Group II (Claims 6-11) were drawn to polynucleotides encoding FEN-1 polypeptides and host cells containing FEN-1 polypeptides. The Applicants elected Group II, Claims 6-11 (FEN-1 polynucleotides) without traverse. Subsequently, the Claims in Group 1 (Claims 1-5) were cancelled and the '283 patent was issued. However, the Applicants failed to

file a divisional application pursuing the subject matter of Claims 1-5 (i.e. FEN-1 polypeptides or claims involving polypeptides). Even if Applicants argue that they were in possession of the alleged invention at the time the original application was filed (which they say in their declaration they were not), Applicants failed to present these claims in the original application or in any divisional or continuation application.

The Federal Circuit has squarely addressed this situation, and flatly rejected an Applicants' attempt to characterize this as acceptable 'error' (*In re Weiler*, 790 F.2d 1576, Fed. Cir., 1986). The court in *In re Weiler*, affirming the Appeal Board's and Examiner's rejections, refused to recognize failure to file a divisional application for either non-elected inventions, or previously unclaimed inventions as an "error" that could be remedied by reissue. In particular, the court states: **"By acquiescing in the examiner's restriction requirement, and failing to file divisional applications** on the subject matter of non-elected claims, Weiler foreclosed (because that was not error) his right to claim that subject matter. If it were not error to forego divisional applications on subject matter to which claims had been made in the original application, it cannot on the present record have been error to forego divisional applications on subject matter to which claims had never been made" (emphasis added, id. at 1582).

Likewise, in the present reissue application, a restriction requirement was issued by the Examiner during prosecution of the original patent, and Applicants failed to file a divisional application on the non-elected claims to FEN-1 polypeptides. Nor did they originally present or otherwise pursue the newly added reissue claims. According to *In re Weiler*, it cannot be viewed as "error" that Applicants elected "to forego divisional applications," either on subject matter to which claims had never been made, or, at best, that relate to the surrendered polypeptide subject matter. Therefore, Federal Circuit precedent makes it clear that the Applicants do NOT have a valid 'error' for this reissue application, rendering this application void.

Thus, the present claims 21-76 must be rejected under 35 U.S.C. 251 for failing to provide an error that can be corrected in reissue. The only way to avoid this rejection is to conclude that the claims are not to the same invention as the surrendered polypeptide claims. Obviously, if the claims are not to the same invention as the surrendered polypeptide claims, they are not the same invention as the issue nucleic acid claims that encode those polypeptides. Therefore, if not the surrendered invention, the claims are to a different invention and cannot be pursued for the reasons described in section IA, above. Either way, the claims are improper and

must be rejected.

III. APPLICANTS HAVE IMPROPERLY MISSTATED THE LAW TO THE EXAMINER

At page 10 of the 2003 Amendment, the Applicants stated the following:

> Pursuant to 35 U.S.C. §251, amendments to the disclosure of reissue application must not introduce new matter into the application. As established previously on the record, matter that does not appear explicitly in an application but that is nonetheless implicitly a part thereof by virtue of an incorporation by reference is not "new." Consequently, the actual text (and figures) of an incorporated reference may be explicitly amended into the description of a reissue application without violating 35 U.S.C. §251.

This is an incorrect statement of the law and is an error by the Applicants. Under the law, in a reissue application, it is impermissible to bodily incorporate essential matter into a reissue application through a reference cited as incorporated by reference for the reasons discussed below.

In the present reissue application, Applicants are attempting to claims methods and kits comprising a "double flap" structure. The specification, as originally filed, provided no description of the "double flap" structure—*i.e.*, the specification did not provide the literal Section 112, written description support, as originally filed, to support claims to a double flap structure because the "double flap" language had not been bodily incorporated into the original specification. Applicants have not disagreed with this point. Instead Applicants have attempted to obtain Section 112, written description support for the claimed essential matter, by bodily incorporating material from a reference cited in the application, into the application. In a reissue case, this is impermissible.

The basis of a reissue application must be an error made by the Applicants in the original prosecution. Applicants could not have claimed the "double flap" structure in the original application because they never incorporated the Harrington & Lieber paper into the specification during the original patent prosecution. Failure to incorporate the Harrington & Lieber paper during the original prosecution cannot form the basis of an error under the reissue rules. Indeed, the failure during the original prosecution to take the steps necessary to provide support for the claimed essential matter proves that the inventors did not believe that the "double flap" was part

of their invention or that they appreciated any use for it at all. The "double flap" that is the major focus of all of the pending new claims appears in the Harrington & Lieber reference as an unhighlighted control experiment with no described use or utility. Had the inventors appreciated the "double flap" as part of the invention, they would have described it in the specification in a manner that would have allowed them to claim it. Under the law, reissue cannot correct the failure to recognize the invention (*i.e.*, failure to recognize the invention is not error—instead it **defines lack of written description**).

MPEP 1402 provides four bases for 'error' in filing a reissue application: "(A) the claims are too narrow or too broad; (B) the disclosure contains inaccuracies; (C) applicant failed to or incorrectly claimed foreign priority; and (D) applicant failed to make reference to or incorrectly made reference to prior copending applications" (*emphasis added*, MPEP 1402). Failure to recognize one's own invention is not among these acceptable bases. MPEP 1402 is clearly discussing the scope of the claims as an error, not the failure to recognize totally separate inventions. It would be unprecedented to allow Applicants' failure to recognize the invention or the presentation of separate and distinct claims to serve as 'error' for this reissue application.

In view of the above discussion, Applicants' incorrect statement of law is revealed. On page 12 of the 2003 Amendment, Applicants argue:

> to demonstrate that Claims 7-73 did not violate 35 U.S.C. §251, Applicant articulated the legal standard by which *amendments of claims* are assessed under 35 U.S.C. §251. In sum, Applicant argued the following:
>
> (1) that the issue of whether amended or *new claims* in a reissue application run afoul of the "new matter" prohibitions of 35 U.S.C. §251 is assess by determining whether the new claims are adequately supported by the disclosure of the patent as originally filed ("original disclosure") in the manner prescribed by 35 U.S.C. §112, ¶1;
>
> (2) that amended or new claims in a reissue application are adequately supported under 35 U.S.C. §112, ¶1 when the original disclosure reasonably conveys to skilled artisans that the inventor invented the subject matter of the amended or new claims; and
>
> (3) that by virtue of an incorporation by reference, the original disclosure of the instant reissue application that can be relied upon for written description support under 35 U.S.C. §112, ¶1 includes not only the actual text of the issued patent, but also the text and figures of the incorporated H&L article (and any other incorporated references).
>
> In fact, the only reason the incorporation by reference was discussed at all in connection with Claims 7-73 was to establish that the text and figures of the incorporated H&L article could be relied upon for purposed of establishing that the original disclosure adequately supported Claims 7-73 under 35 U.S.C. §112, ¶1, and hence 35 U.S.C 35

U.S.C. §251.

While individual statements above are a correct assessment of the law, the combination is applied in an incorrect manner. It is true under heading (1) that "new matter" is assessed by looking at the original disclosure. In the present case, the original disclosure was deficient under 35 U.S.C. §112 because it did not provide direct support for the claimed essential elements (i.e., it did not bodily incorporate the Harrington and Lieber reference into its text and therefore cannot support claims to "double flap" structures). It is true that new claims in a reissue application are adequately supported under 35 U.S.C. §112, ¶1 when the original disclosure conveys that the inventors were in possession of the invention, although in the present case, the original application does not convey that these inventors invented "double flap" methods and kits, because the original application is silent on these elements and cannot properly support claims to them. Statement (3), however, is false as applied to reissue. While this statement may be true under certain circumstances during the original prosecution (in the present circumstances it is not, for the reasons of record), it is never true in reissue. It is not permissible to bodily incorporate essential material during reissue to meet 112 requirements when that material was not bodily incorporated in the original application. This is not an error under reissue law and is not a problem that reissue can correct. As discussed above, it defines lack of written description.

To support their position, Applicants provide a quote from the *Moba v. Diamond Automation* case. What the Applicants do not tell the Examiner is that this case (attached hereto for the Examiner's convenience) says nothing about the law of new matter or written description as it applies to incorporation by reference **in a reissue proceeding** and therefore is not helpful in addressing the main issue—Applicants' improper attempt to add new matter during a reissue proceeding. To the extent there is any relevance to the *Moba v. Diamond Automation* case in the present reissue, the *Moba* decision, like any number of other cases, highlight that the inventors of the present application fail the Section 112 requirements for the current reissue claims. *Moba*, quoting the *Amgen* case (*Amgen Inc. v. Hoechst Marion Rouseel Inc.*, 314 F.3d 1313, 1330 (Fed. Cir. 2003)), states:

> The purpose of the written description requirement is to prevent an applicant from later asserting that he invented that which he did not; the applicant for a patent is therefore required 'to recount his invention in such detail that his future claims can be determined

to be encompassed with his original creation.'"

In the present case, Applicants did not provide an original disclosure that can support the present claims.

The named inventors signed a declaration in the original case attesting to the fact that they understood the contents of the application. They swore in their reissue declarations that "at the time the original patent issued" that they failed to recognize the alleged patentable subject matter now sought to be claimed. This is clearly the case since the original specification did not provide the express support under 112 requirement for the reissue claims. One can only conclude that the named inventors did not conceive of the reissue claims - if they *ever* did - until after the original patent issued (*i.e.* February 23, 1999). The law regarding conception has been stated by the Federal Circuit as follows:

> "[f]or conception, we look not to whether one skilled in the art could have thought of the invention, but whether the alleged inventors actually had in their minds the required definite and permanent idea" (*emphasis added*). As noted in *Burroughs Wellcome Co. v. Barr Laboratories*, 40 F.3d 1223, 1231 (Fed. Cir., 1994),

Applicants' misstatement of the law is improper and, when examined, only further highlights that the original application demonstrates a lack of possession of the invention now claimed in the reissue application. Reissue cannot be used to capture an invention that was not properly disclosed in the original specification.

IV. APPLICANTS HAVE IMPROPERLY MISCHARACTERIZED THE SPECIFICATION WITH RESPECT TO THE 5',3'-DOUBLE FLAP STRUCTURES

On page 15 of the 2003 Amendment, Section F, Applicants mischaracterized the specification and/or misunderstands the issue at hand. The Examiner's rejection properly argued that the addition of the "double flap" to the specification is new matter (it is new matter both in the context of 35 U.S.C. 251 for the reasons described in Section II above and because it is new matter independent of the reissue context). The Applicants admit that the original specification explains that 3' flaps cannot be cleaved.[3] However, the Applicants argue that the present claims are directed to double flaps and not 3' flaps and that, therefore, the discussion of 3' flaps in the

specification is not relevant. Applicants then argue that the incorporated-by-reference Harrington & Lieber article shows that double flaps are cleavable. Applicants repeat these same arguments in the 2004 Amendment as well.

What Applicants fail to understand (or feigns not to understand) is that the issue at hand relates to whether the incorporation by reference is proper in the first place—*i.e.*, whether the original specification's disparagement of 3' flaps is compatible with Applicants attempt to incorporate: 1) structures from largely uncharacterized control experiments showing double flap structure that have no relevance or use described in the Harrington & Lieber paper; as 2) the centerpiece of diagnostic methods in a specification that teaches away from the use of 3' flaps. The point that Applicants are missing or side-stepping is that such an incorporation-by-reference changes the focus of the specification and therefore is not proper. Whether the enzymes can cleave a 5' flap in the presence of a 3' flap is irrelevant. What is relevant is that the original specification distances its methods from 3' flap structures, and therefore provides no basis for incorporating material by reference that provides the opposite teaching. This issue once again highlights the fact that the Applicants were not in possession of the invention in the original application. If they intended to cover double flaps in the original specification, they would have described the 3' flaps as being useful in conjunction with the 5' flaps. They did not—in fact, they did the opposite ("FEN-1 specifically cleaves 5' flap structures and nicked DNA but does not 3' flap structures" from col. 19, lines 28-29, in section entitled "Overview"; "FEN-1, which specifically cleaves 5' flap structures but not 3' flap structures." from col. 50, lines 64-65, in section entitled "Experimental Examples"). Thus, the Applicants have improperly added new matter to the specification and claims. Even if improperly permitted to add this matter, for the reasons discussed in Section II of this documents, the claims are still impermissible under 35 U.S.C. 251 because this new matter was not in the original specification and is directed to a different invention than that originally described or claimed.

V. AMENDING *DEPENDENT* CLAIMS DOES NOT OVERCOME THE EXAMINER'S PROBE LENGTH WRITTEN DESCRIPTION REJECTION

In the November 2003 Office Action, the Examiner rejected Claims 21-25, 31-35 and 51-68 for lack of written description. Part of the Examiner's rejection was premised on the fact that

[3] The Applicants' admission is repeated at page 16 of the 2004 Amendment.

flap strand lengths of 1 and 10 nucleotides (for 3' flaps) and 20 nucleotides (for 5' flaps) are not representative of the range of nucleotide probe flaps claimed (see, November 18, 2003 Office Action, page 7-8). The Examiner appears to be astutely pointing out that, even if the double flap structures from Figure 5 of the H & L paper are incorporated by reference, only two species of the 3' flap are described (1 nucleotide and 10 nucleotides in length) and only one species of the 5' flap (20 nucleotides in length) **in the double flap context** (which is certainly not enough written description to reward the Applicants with claims having *any* 3' or 5' flap length within a double flap structure). The length of the two 3' flaps and one 5' flap are shown in New Figures 11 and 12.

Protestors believe the Examiner's rejection is well founded as the Specification fails to teach that FEN-1 polypeptides will resolve double-flaps structures with varying flap lengths. For example, the Specification leaves it unresolved whether the 5' flap in a double-flap structure always has to be 20 nucleotides in length for a FEN-1 polypeptide to resolve this structure. Also for example, the Specification fails to indicate if different FEN-1s require 5' or 3' flaps that are a certain length. Protestors submit that providing a single 5' flap length (20 nucleotides), two 3' flap lengths (1 and 10 nucleotides) and a single FEN-1 (murine FEN-1) and asserting generic claims not limited to any particular 5' or 3' flap lengths (and not limited to a particular FEN-1) should cause such claims to be properly rejected for lack of written description (as indicated by the Examiner).

In response to this rejection, in the 2004 Amendment, Applicants amended certain *dependent* claims and added other *dependent* claims. In particular, in regard to 3' flaps, Applicants amended dependent claims 31, 56, and 62 to recite that the 3' flap is exactly 10 nucleotides in length (See 2004 Amendment, page 15). In regard to 5' flaps, Applicants amended dependent claims 33, 58, and 64 to recite that the 5' flap is 1-5 nucleotides in length and added new dependent claims 74-76 to recite that the 5' flap is exactly 20 nucleotides in length (See 2004 Amendment, page 15). Applicants' amendments, however, are insufficient to remove the Examiner's rejection.

First, in an attempt to broaden the single 20 nucleotide 5' flap species in the H & L paper, Applicants also cited column 46, lines 46-58 of the patent for teaching 5' flaps 1-5 nucleotides in length. The 5' flaps that are 1-5 nucleotides in length, however, are NOT in the double-flap context. As such, citing these, or any other, 5' flap lengths does not teach anything about 5' flaps

that can be successfully employed in the claims (e.g. successfully resolved as part of double-flap structure when exposed to a FEN-1 polypeptide). Citing this section of the Specification, however, does highlight the fact that one skilled in the art cannot assume that any flap length can be employed (*i.e.* empirical results are needed as indicated in this section of the Specification). This highlights why the single 20 nucleotide 5' flap cited by the Applicants in the double-flap context (using murine FEN-1) is not enough to teach a genus, and why the Examiner is correct in suggesting that the claims should be limited to 5' flaps that are 20 nucleotides in length.

The second reason Applicants' "amendment" is not sufficient to overcome the Examiner's rejection is the fact the Applicants amended or added *dependent* claims - without limiting the *independent* claims in a similar fashion. In other words, Applicants are still attempting to encompass 3' and 5' flap lengths (in a double-flap structure) that can be *any* length - even though they have only disclosed[4] two 3' flap lengths and one 5' flap lengths in the double-flap context (using the murine FEN-1). The Examiner's rejection included all three independent claims, but these claims still broadly encompass any 3' and 5' flap lengths since the Applicants did not amend the Independent claims. As such, Protestors urge the Examiner to maintain the probe length rejection or require the Applicants to amend Independent Claims 21, 51, and 59 to include a 5' flap length of exactly 20 nucleotides and a 3' flap length of either 1 or 10 nucleotides.

[4] Protestors note that Applicants have not actually disclosed any double flap structures or flap lengths as the incorporation by reference being attempted is not legally proper.

CONCLUSION

For these reasons discussed above, in addition to the issues discussed in the previous Protests, Protestants believe that Claims 21-76 in the reissue application should be rejected by the Examiner.

Applicants are attempting to rewrite the patent laws in their attempt to now patent subject matter that was not part of their original specification or invention. Protestants encourage the Examiner not to allow this rewriting or reinterpretation of the patent laws. Such a task is left to Congress or the Courts.

Dated: August 13, 2004

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